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| 10/559,373 | 02/07/2006 | Nobuaki Sumiyoshi | 2005_1741A | 3630 |

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| EXAMINER | |
|---|---|
| KASSA, TIGABU | |

| ART UNIT | PAPER NUMBER |
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| 1619 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/559,373 | SUMIYOSHI ET AL. | |
| | Examiner | Art Unit | |
| | TIGABU KASSA | 1619 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *24-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/22/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

This Office Action is in response to the amendment filed May 20, 2010. **Claims 24-37 are pending. Claims 24-37 are under examination in the instant office action**. Claims 1-23 are cancelled. Claims 24-37 are newly added. Applicant's amendment has necessitated a new ground of rejection.

### *Request for continued examination*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/20/10 has been entered.

### *Moot Rejections/Objections*

All rejections and/or objections of claims 16-21 and 23 cited in the previous office action mailed on January 22, 2010 are moot, because said claim(s) has/have been cancelled.

### *Withdrawn rejections*

Applicant's amendments and arguments filed on 05/20/10 are acknowledged and have been fully considered. All rejections applied in the previous office action are hereby withdrawn as a result of applicants claim amendments.

### *New Rejections*

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

**Claims 24-25 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Segers et al. (US Patent 5383324) in view Veech (US Patent No. 4663166).**

***Applicant Claims***

Applicant claims in instant claim 24 an aseptic combination preparation to be mixed at the time of use by opening a partition wall which separates two or more chambers of a container comprising a first solution containing a potassium salt in a first chamber and a second solution containing a potassium salt in a second chamber, wherein the first solution and the second solution each have the same potassium salt and each have a potassium ion concentration of about 13 to 35 mEq/L. Instant claim 25 recites the aseptic combination preparation according to claim 24, wherein the same potassium salt is at least one selected from the list recited in the claim. Instant claim 28 recites the aseptic combination preparation according to claim 24, wherein the first solution further contains a sodium salt and/or a bicarbonate salt. Instant claim 29 recites the aseptic combination preparation according to claim 24, wherein the second solution further contains a sodium salt.

***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

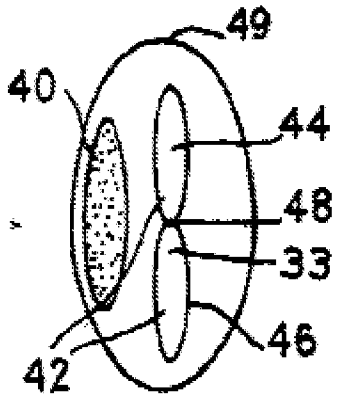
Segers et al. teach a system designed to be used for any medical procedure requiring bicarbonate, and especially for peritoneal dialysis comprising a container with two chambers (see Figure 4). Segers et al. teach the chambers as follows (column 7, lines 19-26):

upper chamber 44 and a lower chamber 46.

In an embodiment, the multi-chamber container 42 has a frangible seal 48 between the upper chamber 44 and the lower chamber 46. Opening the frangible seal 48 provides fluid communication between the upper chamber 44 and the lower chamber 46. The multi-chamber 42 houses at least two non-compatible solutions that after mixture will result in a ready-to-use dialysis solution. An example of the multi-chambered container 42 is set

**Segers et al. teach although all of the systems disclosed herein are designed to be used for any medical procedure requiring bicarbonate, and especially peritoneal dialysis, the embodiment illustrated in FIG. 4 is conveniently used for CAPD** (column 7, lines 30-34).

FIG. 4




To this end, in an embodiment, **the upper chamber 44 contains calcium chloride and magnesium chloride, whereas the lower container 46 contains bicarbonate (column 7, lines 34-37)**. **In a preferred embodiment, the upper chamber 44 can further include sodium chloride, potassium chloride, dextrose and dextrose polymers (column 7, lines 37-39**. **Likewise, the lower chamber 46 can further include sodium chloride, potassium chloride, amino acids, peptides and glycerol** (column 7, lines 39-41).The examiner notes that from the above teachings the required solutions of a potassium salt and sugar in one chamber and a potassium salt and an amino acid in another chamber are clearly meet.

Segers et al. teach, for example, in an embodiment, when the solution contained in the upper chamber 44 is mixed with the solution contained in the lower chamber 46, the subsequent peritoneal dialysis solution has the following composition: 15.0 to about 45.0 (mmol/L)

bicarbonate; 90.0 to about 110.0 (mmol/L) chloride; **90.0 to 142.0 (mmol/L) sodium**; 0.0 to about 2.0 (mmol/L) calcium; 0.0 to about 1.0 (mmol/L) magnesium; **0.0 to about 3.0 (mmol/L) potassium**; 0**.0 to about 4.0% amino acids; 0.0 to about 4.0% peptides**; 0.0 to about 4.0% glycerol; **0.0 to about 5.0% dextrose; and 0.0 to about 10.0% dextrose polymers**. Segers et al. teach ten grams of **sodium bicarbonate** is enough to generate two liters of carbon dioxide and will therefore, in the systems set forth in FIGS. 2-5, stabilize a bicarbonate solution for several months to years (column 5, lines 62-66).

***Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)***

Although Segers et al. teach the incorporation of potassium in concentration 0.0 to about 3.0 (mmol/L) in the final mixture, which the examiner believes would be expected to behave similarly as in the instantly recited concentration ranges, Segers et al. do not explicitly teach the concentrations of potassium ion in each chamber from about 13 to 35 mEq/L. Segers et al. is silent with regard to the concentration of the potassium ion in each chamber. These deficiencies are cured by the teachings of Veech.

Veech teaches electrolyte solutions are provided which are useful in electrolyte and fluid therapy, parenteral nutrition, and dialysis (see abstract). **Veech teaches electrolyte solution compositions for example in column 35 table III on the example with broader range contains 0 to about 90 millimoles/L. Veech teaches the electrolyte solutions of such Table III, as indicated above, are useful in such applications as intravenous administration for**

**replacement of electrolytes and fluids, for parenteral nutrition, for dialysis, and the like**

(column 35, lines 62-65).

***Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)***

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention was made to modify the teachings of Segers et al. via incorporating potassium ion in concentration range as recited in instant claim 24 because Veech teaches an electrolyte solution that contains 0 to about 90 mEq/L of potassium ion. An ordinary skilled artisan would have been motivated to incorporate potassium in concentration range as recited in instant claim 24 because Veech teaches that **the electrolyte solutions of such Table III, as indicated above, are useful in such applications as intravenous administration for replacement of electrolytes and fluids, for parenteral nutrition, for dialysis, and the like** (column 35, lines 62-65). Furthermore, in the case where the claimed ranges for the amounts of the ingredients "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Similarly, a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). Furthermore, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA

1955). One of ordinary skill in the art would have had a reasonable chance of success in combining the teachings of Segers et al. and Veech because both references teach electrolyte solutions for use in dialysis.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

**Claims 27 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Segers et al. (US Patent 5383324) in view of Veech (US Patent No. 4663166) as applied to claims 24-25 and 28-29 above, and further in view of Nakamura et al. (US Patent 6867193).**

***Applicant Claims***

The claimed subject matters of instant claim 24 are set forth above. Instant claim 27 recites the aseptic combination preparation according to claim 24, wherein the amino acid is at least one selected from the list recited in the claim. Instant claim 30 recites the aseptic combination preparation according to claim 24, wherein the container is a plastic container.

***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

The teachings of Segers et al. and Veech are set forth above.

***Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)***

Segers et al is silent whether the material is plastic or not. Segers et al. even if they teach the incorporation of amino acids, Segers et al. is silent on specific list of amino acids. These deficiencies are cured by the teaching of Nakamura et al.

**Nakamura et al teach a preparation contained in a plastic bag with two chambers which are separated by a seal which can be opened in order to mix the contents of the two chambers**. One chamber contains a solution of amino acids and the other contains albumin (column 4, lines 18-36). Branched amino acids in the present invention include amino acids having a branched alkyl group in the side chain thereof, that is, L-valine, L-leucine or L-isoleucine, and any of these amino acids can be used. Other amino acids are aliphatic amino acids such as straight-chain amino acids (glycine, L-alanine), hydroxy amino acids (L-serine, L-threonine), acidic amino acids (L-aspartic acid, L-glutamic acid), amido-type amino acids (L-asparagine, L-glutamine), basic amino acids (L-lysine, L-hydroxy lysine, L-arginine), and sulfur-containing amino acids (L-cystein, L-cystine, L-methione) (column 2, lines 26-40).

***Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)***

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention was made to modify the teachings of Segers et al. by incorporating the specific amino acids recited in instant claim 27 because Nakamura et al. teach medicinal preparations which contain for example amino acids as specified above contained in two or more adjacent chambers which are mixed just prior to use. It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention was made to use plastic

containers to deliver such electrolyte solutions in dialysis because plastic are conventionally known in the art for holding solutions. An ordinary skilled artisan would have been motivated to incorporate these amino acids because they are conventionally known and are sources of proteins. An ordinary skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings, because both Segers et al. and Nakamura et al. teach medicinal preparations which contain for example amino acids contained in two or more adjacent chambers which are mixed just prior to use.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

**Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Segers et al. (US Patent 5383324) in view of Veech (US Patent No. 4663166) as applied to claims 24-25 and 28-29 above, and further in view of Stone et al. (US Patent 4489097).**

***Applicant Claims***

The claimed subject matters of instant claim 24 are set forth above. Instant claim 26 recites the aseptic combination preparation according to claim 24, wherein the same potassium salt is dipotassium hydrogen phosphate.

***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

The teachings of Segers et al. and Veech are set forth above.

***Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)***

Although Segers et al. teach the incorporation of potassium chloride as one of the salts, Segers et al. do not teach potassium dihydrogen phosphate as the potassium salt. This deficiency is cured by the teaching of Stone.

Stone teaches sterile compositions intended for administration to humans or lower animals to minimize bacterial and mycotic contamination which can cause infections associated with the medical and veterinary use of such compositions (see abstract). Stone teaches the **compositions are useful for all purposes where contact between electrolyte solutions or nutrient solutions and blood or internal organs or systems is required, e.g., as plasma expanding agents, as the fluid medium in kidney dialyzers, as irrigation solutions for cleansing wounds, as respirator solutions, and the like** (column 5, lines 50-58). Stone teaches an intravenous electrolyte solution containing potassium dihydrogen phosphate, potassium chloride, and other salts and sugar (column 12, example 1, lines 45-60).

***Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)***

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention was made to modify the teachings of Segers et al. by incorporating potassium dihydrogen phosphate as recited in instant claim 26 because Stone teaches in a similar electrolyte solution incorporating potassium dihydrogen phosphate as set forth above. One of ordinary skill in the art would have been motivated to substitute potassium chloride with

potassium dihydrogen phosphate because they are functionally equivalent potassium salts. An ordinary skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings, because both Segers et al. and Stone teach similar electrolyte solutions that can be used in dialysis containing potassium salts, sodium salts, and sugar.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

**Claims 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Segers et al. (US Patent 5383324) in view of Nakamura et al (US Patent 6867193).**

***Applicant Claims***

Applicant claims in instant claim 31 recites an aseptic combination preparation to be mixed at the time of use by opening a partition wall which separates two or more chambers of a container, comprising a first solution containing a sodium salt and a sugar in a first chamber and a second solution containing a sodium salt and a bicarbonate salt in a second chamber, wherein the first solution and the second solution each have the same sodium salt and each have an osmotic pressure ratio of about 1 relative to physiological saline. The dependent claims thereof recite types of salts that can be incorporated in the chambers and the container being a plastic.

***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

The teachings of Segers et al. are set forth above.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)***

Segers et al. do not teach an osmotic pressure ratio of about 1. Segers et al. is also silent whether the material is plastic or not. These deficiencies are cured by the teaching of Nakamura et al.

**Nakamura et al teach a preparation contained in a plastic bag with two chambers which are separated by a seal which can be opened in order to mix the contents of the two chambers. One chamber contains a solution of amino acids and the other contains albumin (column 4, lines 18-36). In example 1, the osmotic pressure ratio between the amino acid and the albumin containing solutions was 2.8-3.3 (column 5, lines 8-14).**

***Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)***

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention to ensure that the osmotic pressure ratio between the two solutions because Nakamura et al. teach an osmotic pressure ratio of 2.8-3.3 between two solutions of a medicinal preparation contained in adjacent chambers until mixing just prior to use. An ordinary skilled artisan would have been motivated to adjust the osmotic pressure of the solutions because the osmolality of medicinal preparations is important for the safety and efficacy of the preparation. Moreover, the instant specification points out that the administration of solutions of the incorrect osmolality due to medical error is already a well known medical problem. The examiner notes that the original specification does not contain a definition to the term "about".

The examiner contends that 2.8-3.3 reads on and renders obvious about 1. Similarly, a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). Furthermore, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). An ordinary skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings, because both Segers et al. and Nakamura et al. teach medicinal preparations which contain for example amino acids contained in two or more adjacent chambers which are mixed just prior to use.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

## Conclusion

Claims 24-37 are rejected. Claims 1-23 are cancelled. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne P. Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa 05/20/10
/YVONNE L. EYLER/

Supervisory Patent Examiner, Art Unit 1619